Home Visit
SOF Visit 4
Overview and protocols

I. Overview

The purposes and order of the home visit are as follows:

- Obtain informed consent
- Administer the cognitive function tests (Mini-mental, digit symbol)
- Conduct the physical examination and performance tests
- Review subject's current medications
- Draw blood
- Review functional status questionnaire
- Review clinic use questions of the take home questionnaire
- Ask one more time if participant would be willing to come in to the clinic just for follow-up BMD measures.
- Provide the subject with an environmental Home Safety checklist

Instructions and Questionnaires

The take home and clinic self-administered questionnaires should be sent to the participant at least one week prior to the home visit. Home visit participants do not need to fill out the dietary assessment portion of the take home. If the participant does end up coming in to the clinic, diet should be collected at that time. Tell the participant to complete the questionnaires by the time of the visit.

In addition, instructions for participants on how to prepare for the home visit are mailed one week prior to the visit. Instructions cover the following:

Footwear: To eliminate the effect of different footwear on test performance, these tests should be performed in tennis shoes or other shoes with minimal or no heels. The participant should not wear slippers. The participant may perform the tests in stocking feet if appropriate footwear is not available and floor surface is not slippery.

Clothing: Participants should wear comfortable, loose fitting slacks and tops. Skirts and dresses are discouraged.

Medications: Participants are asked to collect pill bottles and containers for all medications they have taken in the past 30 days for review by the examiner. If they no longer have the container, they should try to locate a copy of the prescription, or write down the name and/or reason for taking the medication.

Questionnaire: Participants are asked to complete as much of the questionnaires (take home and clinic self-administered) as possible prior to the home visit. Participants should flag any questions that they did not understand or have questions on.

Informed consent: Participants are asked to review the informed consent prior to the visit. Any questions can be reviewed with the interviewer. This procedure may differ slightly clinic to clinic.

Spot urine: We will be asking participants to collect the first void upon waking (a container can be included in the mailing prior to visit) on the day of her home visit and keep it refrigerated. If the participant does not collect a first void, then collect a specimen during the visit.

II. Hazardous conditions and health/social service needs.

If a potentially dangerous situation is encountered in a home visit, such as an uncontrollable dog, someone carrying a weapon, an abusive person, or threatening neighbors, **leave the situation**. If it appears to be a situation that is easily resolved, call the home from another location and discuss it with the participant. If the situation cannot be resolved, cancel the interview.

The home visit staff should be alert to health or life-threatening situations in the home that may need to be investigated by social service or health care personnel. Examples include: hunger/malnutrition, extremely unsafe dwellings (fire, electrical hazards), extreme isolation, unattended serious health problems, severe unattended cognitive impairment, threat of suicide or violence, or abuse.

Serious health or psychiatric problems should be referred to the study physician at your clinic who should contact the subject's physician.

Nonemergency issues regarding safety, competency, or other such problems should be discussed with the participant. If the participant is receptive to outside help, say that you will make some inquiries about available services in the area and get back in touch with the participant to discuss the next step.

Record any problems encountered during the home visit on the Home Visit Problem Report page of the interview form.

III. Questionnaires and interviews

The questionnaires for the home visit are the same as for the clinic visit except for the following:

- Take home:
  Home visit participants do not fill out the diet portion
- Examination form:
  - Only for those exams completed during the home visit.
  - Cover page has added fields for time BRI blood drawn, to be filled out at the home and processed, to be filled out at the clinic.
  - Gait speed form has an added field for length of walking course.
- A home visit problem report form is included.

The interview should be performed with both the participant and the interviewer seated comfortably. Sit close enough to the participant to communicate effectively and maintain eye contact. Sit at the same level as the participant. Speak clearly and loud enough for the participant to hear without having to repeat what was said.

If others are present in the residence, try to conduct the interview in relative privacy. However, if a spouse wants to be present, particularly if they can be helpful with a subject that has hearing or cognitive problems, then the interviews may be conducted in their presence.

The home visit assessment covers the following topics, in the order listed below.

1 - Consent: Review consent forms with subject and obtain informed consent.

2 - Examinations: 1 - chair stand, 2 - grip, 3 - gait, 4 - balance, 5 - height/weight, 6 - spirometry.

3 - Cognitive function tests: Digit symbol and Mini-mental exam. Follow protocol same protocol as for the clinic visit.

4 - Medications: Review and complete the medication sections of the questionnaire, based on the subject's current medications. Follow same protocol as used in the clinic.

5 - Blood draw: Draw 2 10 mL of blood for BRI. Record time drawn on the exam cover sheet. The order of this item can be shifted as appropriate to allow adequate clotting time but minimal time on ice.

6 - Functional status: Complete the functional status section of the clinic questionnaire. Follow same protocol as used in the clinic.

7 - Questionnaire review: Review take home questionnaire, completing questions with clinic use boxes. Review the self-administered questionnaire for errors and missing data. Complete missing and incorrect items with the participant's help. If there is not time for review of these questionnaires during the home visit, then inform the participant that you would like to complete them over the phone. Set up a mutually agreeable time for completion.

8 - Home Safety Checklist: Explain and give participant a Home Safety Checklist.

IV. Examinations

List of equipment: The following is the list of equipment needed to carry out the assessment of physical function in the home.

- measuring tape in metric units
- 20 ft carpenters tape for measuring the walking course or premade 3,4,5, and 6 meter walking course markers
- right angle for height
- portable scale
- spirometer
- stopwatch
- floor markers for gait test (starting and ending line, X for target)
- grip strength dynamometer
- blood draw supplies
  chux
  dirty needle disposal unit
- urine container (sent ahead)
- small ice chest filled with ice for blood and urine specimens
- armless, straight backed, hard seated chair (if none available in the home fitting this description, choose the chair with the hardest seat of those available)
- trash bag
- pencils - at least 2
- post-its
- clipboard
- extra set of forms

Equipment calibration: The scale, grip dynamometer, and spirometer should be calibrated the morning of any scheduled home visit day. Keep a log of these calibration checks at the clinic.

The following home visit protocols for home visit examinations have been adapted from the SOF Visit 4 protocol.

Instructions to participants: To some participants, the detailed verbal instructions may seem pedantic or unnecessary. It may help to say that you are going to explain each test to the participant in detail since this is the best way to make sure that everyone does the test in a similar manner. The individual examiner must determine whether a participant understands what is required and provide the appropriate level of instruction.

Follow the scripts as closely as possible, to describe the tests and how to perform it properly. Do not provide additional encouragement beyond the language provided by the detailed instructions.

Functional status screening: Ask each participant "Do you have any problems from recent surgery, injury, or other health conditions that might prevent you from standing up from a chair or walking up steps?" If the answer is yes, record on the scoring form, and after you describe each test, discuss with the participant whether he/she should attempt the test given his/her physical problems.

Refused/unable: If a test is not attempted because the participant refuses, for whatever reason, record "refused" on the scoring form. If possible, record a reason for the refusal.

If a test is attempted but cannot be completed or scored (e.g. fear of falling or pain), record "unable" on the scoring form and give the reason (e.g. fear, pain, etc.).

Walking Aids: Walking aids may be used for the usual walk test. Walking aids should not be used for the tandem stance or chair stand tests. If aids are used for a test, this should be recorded on the scoring form.

Demonstrations: Demonstrate each test for the participant, as indicated in the detailed instructions.

Practice trial: Allow the participant a practice trial where indicated in the detailed instructions.

Rest: The participant should be allowed to rest between tasks if out of breath or fatigued during the assessments.

Safety Precautions: The detailed instructions describe how to safely administer the tests including instructions on how to support the participant if required.

- Obstructions that could cause an accident should be moved, removed, or avoided.

- For tests where loss of balance is a possibility, use the following safety precautions. Position yourself at the subject's side, slightly behind her. Your hands should be positioned on either side close to but not touching the subject's waist. If the subject loses balance, stabilize her by grasping the trunk. If the subject begins to fall, reach under her shoulders from behind and slowly ease her down to the floor.

If the subject is not injured, help her to arise by placing a chair next to the subject and having her get down on all fours. Have the subject support herself on the chair as you help lift under the shoulders. Do not try to lift the subject directly from the floor alone.

If the subject is injured, call a local emergency number (911).

EXAMINATION PROTOCOLS

A. NEUROMUSCULAR PERFORMANCE: STAND UP FROM A CHAIR, GRIP STRENGTH, GAIT TEST, TANDEM STAND

Footwear: The subject should wear comfortably fitting shoes for each of the tests in this section. Do not perform these tests with the subject wearing high heels (≥ 1 inch) or slippers. If no other options are available, perform the tests with the subject in stocking feet or barefoot.

I. TIMED CHAIR STAND

1. Description:

This tests the subject's ability to stand up from a standard chair without using arms for support and the time required to stand up from a chair five times, measured with a stopwatch.

2. Equipment:

A straight-backed, armless, hard seated chair (such as a hard wooden) approximately 45 centimeters (18 inches) high at the front edge. The seat should incline no more than a few degrees from front to back.

Stopwatch.

Place the back of the chair against a wall to steady it. Stand next to the participant to provide assistance in case she loses her balance.

3. Measurement Procedures:

a) Have the participant sit in the chair, assuming the position from which she would normally stand up from a chair (but no more than half-way forward on the seat of the chair) with the feet resting on the floor and the arms folded across the chest. Say:

"The next test measures the strength in your legs. Please fold your arms across your chest. When I say 'Ready? Stand!', please stand up straight as rapidly as you can five times without stopping in between and without using your arms to push off. After standing up each time, sit down and then stand again without stopping. Now watch while I demonstrate the correct way and the incorrect way to stand." (*demonstrate both for the participant, exaggerating the incorrect way).*

Then ask her to stand up one time for practice.

b) When the subject is properly seated after practicing say

" Okay, now I'll be timing you with the stopwatch as you stand up 5 times. Please try to do this as fast as you can while still feeling safe. Ready! Stand."

Start timing when the command "Stand" is given. Count out loud as she arises each time, up to 5. Stop the stopwatch when she has straightened up completely the fifth time.

c) If she is unable to arise without using her arms say:

"O.K., try to stand up using your arms to push off."

Be sure to record arm use on the form.

d) If the participant fatigues before completing 5 stand-ups, confirm that she can't do any more by asking:

"Can you continue?".

If she says yes, keep timing. If she says no, record that she could not complete five stand-ups and do not record a time for her.

e) For those participants who completed all 5 stands, ask:

"Was that as fast as you can do it while still feeling safe?"

If participant says no - then ask her to repeat the test emphasizing that she should stand *as fast as she can while still feeling safe.*

Record the time for the second trial.

f) Record:

i) whether she can stand up five times without help,

ii) arm use (none, some stands, all stands),

iii) the time to complete five stands to the nearest tenth of a second.

II. GRIP STRENGTH WITH DYNAMOMETER

1. Equipment: Preston Grip Dynamometer, Jackson MI (Takei Kiki Kogyo; "Smedley" Lightweight Hand Dynamometer) or the dynamometer from baseline (just be sure to check calibration). The handle should be adjusted so that the individual holds the dynamometer comfortably.

2. Measurement Procedure:

a) Grip strength will be measured in both arms unless the participant has had a recent flare-up of extreme arthritis or recent surgery.

• For each hand, determine if the subject has an acute flare-up of arthritis in the hand, or surgery in the hand or wrist in the past 3 months (12 weeks). If the subject has had an acute flare-up of arthritis or is less than 13 weeks post fusion, arthroplasty, tendon repair, synovectomy, etc. then do not test grip on the affected side.

"Have you had a recent worsening of pain or arthritis in your hands, or have you had surgery on your hands in the past 3 months (12 weeks)?"
If yes, test grip strength in unaffected side only. Mark "weakened" on the form for the affected side only.

"This device measures your arm and upper body strength. I will demonstrate how it is done. Bend your elbow at a 90° angle, with your forearm parallel to the floor. Don't let your arm touch the side of your body. Lower the device slowly, taking about 3 seconds, as you squeeze as hard as you can. Once your arm is fully extended, you can loosen your grip."

b) Place the dynamometer in the right hand with the dial facing the palm. The arm should be flexed 90° at the elbow and the forearm parallel to the floor. As you demonstrate, instruct the individual to squeeze the hand maximally while simultaneously lowering the arm on a three second count. The grip should be released when the arm is completely extended, hanging straight at the side.

c) Allow one submaximal practice trial using the right arm.

"Does that feel like a comfortable grip?"

Adjust the handgrip, if necessary.

"Now try it once just to get the feel of it. For this practice, just squeeze gently."

d) Perform two trials on the right side.

"Good. Now this time it counts. Squeeze as hard as you can!"

Record the kilograms pulled from the dial to the nearest 1 kg. Reset the dial. Perform the second trial.

e) Repeat the procedure for the left arm. No practice trial is needed for the left, but ask the subject if the grip is comfortable.

Precautions: The arm should not contact the body. The gripping action should be a slow sustained squeeze rather than an explosive jerk.

f) On the scoring form, there should either be a value for strength attained OR one of the three boxes - refused, unable, or weakened, should be checked. The weakened box should only be checked if the participant has had recent arthritis or surgery on that side.

III. GAIT (WALKING SPEED, STEP LENGTH AT USUAL AND RAPID PACE)

1. Description:

Time required to walk a six meter course (seconds), average step length (centimeters), at usual (2 trials) and rapid (1 trial) pace.

2. Equipment:

Adequate space for the gait test. Identify an obstacle free pathway, as close to 6 meters at possible. If possible, use an area with bare floor or thin (low pile) carpeting. There should be about an extra meter of space on either end of the course for stopping. If space is limited, then the course can be designed to have the participant just walk in one direction, returning to the same starting point for each trial. Less space would be required at the starting line, with just the toes behind the starting line and then at least one meter on the other side of finish line.

Ideally, the walking course will cover just one type of surface (ie bare floor or low pile carpeting). However, if necessary, the course can be set up across two different surfaces to get an adequate length. The participant probably walks these areas in her home on a daily basis and thus they should not incur any undo hazard.

If possible, choose an area where the examiner can view the subject from the side about midway between the end markers, such as by standing in a doorway along a hallway. The examiner may need to walk next to very frail subjects or those with severe postural instability. In this case, choose an area with enough space for two people to walk side by side.

Stopwatch.

Premeasured 3, 4, 5, and 6 meter strings.

Flexible (plastic or cardboard) floor starting and ending line markers, about 1 meter long (marked with a red line at 1/2 meter) and 5 centimeters wide. Place the markers flat across both ends of the obstacle free pathway. Place an X on the other side of the finish line as a goal for the participant to walk to.

3. Subject Preparation:

The participant should be wearing slacks and comfortable walking shoes. She may use a walking aid, but should be encouraged to walk without one.

"Now I am going to observe how you normally walk. If you use a cane or other walking aid and would feel more comfortable with it, then you may use it. However, if possible I would like you to walk without using any aids.

4. Measurement Procedures:

A. WALKING SPEED AND STEP LENGTH, USUAL PACE

a) Ask the subject to stand behind the line at one end of the course, at the red center mark.

"When I say 'begin', I would like you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store. Walk all the way to the X at the other end before you stop.

b) Ask the subject to begin the usual walk.

"Remember, walk at your usual pace all the way past the line at the other end before you stop. Ready? Begin."

Start the stopwatch at the word "Begin" and stop timing when one foot is all the way across the end line. Count the number of steps taken to cover the course. One step is counted when either foot is placed down on the floor, including the first step and the step which first takes a participant's foot completely across the end line.

c) When the participant crosses the end line, ask her to turn around and stand at the end line as before. Or if the same starting line is being used, ask the participant to proceed back to the starting line for a second trial.

"Now we will repeat the same thing (in the other direction). Walk at your usual pace and go all the way to the X at the other end. Ready? Begin."

d) Record time and steps for the two trials.

B. RAPID PACE

a) For the third trial, ask the participant to walk at a rapid but safe pace.

"This time I would like you to walk at a rapid, but safe, pace. Walk as fast as you can while still feeling safe".

b) Record the time and number of steps.

C. RECORD THE LENGTH OF THE WALKING COURSE ON THE EXAM FORM.

IV. TANDEM STANCE SEQUENCE

1. Description:

This is a graded series of timed (up to 10 seconds) static balance tests with the feet side by side, in semi-tandem, and full tandem positions. For the home visit, the trial will be performed with eyes open.

2. Equipment: Stopwatch.

3. Measurement Procedure:

Have the participant stand on bare floor or thin (low pile) carpeting. Do not perform this test on thick carpeting or on loose rugs, such as throw rugs.

POSITION 1. Full Tandem Stance (Eyes Open)

a) Tell the participant,

"This series of tests will assess both the strength in your legs and your balance. First, I would like you to stand with the heel of one foot in front of and touching the toes of the other foot for about ten seconds.

b) Demonstrate the tandem stance for the participant. The participant can place the heel of either the right or left foot in front of and touching the toes of the opposite foot; whichever is more comfortable. Stand next to the participant to help her into the tandem position, supplying just enough support to the her arm to prevent loss of balance. Tell the participant

"You may use your arms to maintain your balance, but try not to move your feet. Try to hold this position until I say stop."

c) When the participant has her feet in the tandem position, ask if she is ready. When her stance has stabilized, let go gently and start timing as you say "Start". Stop the stopwatch after 10 seconds or when the subject steps out of position or touches the examiner for support.

d) Record time to the nearest second.

e) If the participant cannot attain the tandem position at all, or cannot hold it for at least one second, score "tried, but unable." GO TO POSITION 2. If the participant holds the tandem stance for one or more seconds, record the time and GO TO POSITION 2.

f) If the participant holds the tandem position for ≥ 10 seconds, then her test of tandem stand is finished. Proceed to next examination.

B. ANTHROPOMETRY: WEIGHT AND HEIGHT

Rounding convention: Round up at .5 of smallest unit recorded on exam form.

I. WEIGHT IN KILOGRAMS

1. Equipment:

Weight is measured in pounds using a portable scale. Pounds should be converted to kilograms once back at the clinic.

The scale should be calibrated in the clinic prior to each home visit day against 2 50 lb weights, or a 50 kg or 2 25 kg weights.

2. Subject preparation:

Weight is measured without shoes and without outer clothing or heavy sweaters.

3. Measurement Procedure:

a) The participant should stand in the center of the scale with weight equally distributed on both feet and not touching or supporting herself on anything.

"In order to measure your weight, I would like you to remove your shoes (and any heavy outer clothing) and step forward onto the center of the scale."

b) Some participants may require support while being weighed. If it is necessary for the participant to use a cane for support while weighing, weigh yourself with and without the participant's cane, etc., to determine its weight. Subtract the weight of the aid from the participant's weight before recording. In the event that it is necessary for the examiner to support the participant during weighing, provide the minimum support that is safe.

c) Weight is recorded to the nearest pound (half pound if scale allows it). Convert pounds to kilograms for data entry when back at the clinic.

II. STATURE (STANDING HEIGHT)

1. Equipment:

Height is measured in centimeters against a wall using a right angle on the top of the scalp and a measuring tape. Find a blank wall in a room with a bare floor or thin (low pile) carpeting) with adequate space on the side for the examiner to stand to make an accurate measure.

2. Subject preparation: Height is measured without shoes.

3. Measurement Procedure:

a) The participant stands with her back against the wall with the heels together and both heels touching the wall plate. The back (scapulae) and buttocks should be in contact with the wall.

"Please stand against the this wall. Your heels should be together (as close as possible) and both heels should be touching the wall (or molding). Look straight ahead. (If necessary say: I will position your head so that I can measure your height more accurately.)"

b) Be sure that in this position the participant maintains erect posture, i.e., no slouching. Heels should be together with the weight equally distributed and the head in the "Frankfort Horizontal Plane." The line through the lowest point on the inferior orbital margin (orbitale) and the upper margin of the external auditory meatus (tragion) should be horizontal. The right angle is brought down firmly onto the top of the head. It may be necessary, upon occasion, to remove or alter the hairdress of some of the participants. This is necessary for the right angle to make contact with the top of the scalp.

Occasionally, it will be impossible to position the participant's heels, buttocks, scapulae and the back of the head in one vertical plane against the wall and still have her stand naturally and comfortably. If the back is arched due to large buttocks, move the participant forward and have only one part (usually the buttocks) in contact with the wall. Similarly for participants with severe spinal curvature, if the spine is the part that protrudes the farthest, then that should be the part that is touching the wall.

c) Once in position, say:

"Take a deep breath."

Have the participant inhale deeply, again not altering position by, for example, raising the heels off the floor.

d) Stature is measured just before exhaling. Mark the position where the bottom of the right angle touches the wall with a small piece of tape or a post-it.

"Exhale."

e) Ask participant to step away from the wall. Measure the distance from the floor at the base of the wall to the piece of tape. Record height to the nearest tenth of a centimeter.

f) Repeat procedure obtaining second height measure.

C. PEAK EXPIRATORY FLOW PROTOCOL

1. Introduction

Peak expiratory flow, the maximum rate of flow of air expelled during a forced expiration, measures large airway function. It can be measured simply by using an inexpensive portable instrument, the mini-Wright peak flow meter. The measure also provides useful information on the health of the elderly, beyond lung function (see Am J Epidemiol 1989; 130:66-78).

Normal flow rate in a 70 year old SOF participant who has never smoked would be about 300 L/min (liters per minute), and in a smoker, about 250 L/min. There is an age-related decline of about 30 L/min per 5 years of age. Rates vary by body size as well.

These peak flow devices are commonly used in medical practice to monitor patients with asthma.

The measurement is quite simple: you simply ask a woman to take a deep breath, then blow out through the device in one big huff.

2. Equipment

Mini-Wright peak flow meter. Disposable cardboard tubes.

3. Measurement Procedures

It is simplest to demonstrate the use of the flow meter first.

Reset flow meter to zero. Place your mouthpiece (you can color code them for each examiner) on the flow meter. Hold the flow meter at the bottom, level with the ground.

> "This instrument tests lung function. See how I hold it at the bottom? I am going to take a deep breath, close my lips tightly around the tube, and blow out quickly as hard as I can. Think of it as a BIG HUFF. I will blow out air in one big huff, sharply and quickly, and I will stop before I've completely run out of air. (Demonstrate). Now it's your turn."

Reset flow meter to zero. Put on a new mouthpiece in front of the participant, and hand her the device. Have her hold it at the bottom.

> "I would like you to take a deep breath and hold it. Then close your lips tightly around the tube, and HUFF as hard as you can. Just blow out in ONE BIG HUFF and stop blowing before you've completely run out of air. The first two tries will be for practice."

Have her take a deep breath, and watch her close her lips. Make sure she holds her breath.

> "Ready? Huff."

DO NOT LET A PARTICIPANT EMPTY HER LUNGS (this may provoke coughing). **A big huff is sufficient**. If the participant is having problems or is blowing out too much air, correct her right then, before her second practice. Practice is very important for this test and feedback should be given immediately. Reset and repeat practice.

> "Good. Now we will measure it for real, three more times."

Repeat above three times, **resetting to zero,** and checking for secure closure of mouth around the mouthpiece each time. Correct the participant if she needs it. Before each trial, repeat the following two sentences "HUFF as hard as you can. Just one big huff and stop blowing before you've completely run out of air." Record all three measurements (to the nearest 10 L).

If you the participant is getting scores in the low one hundreds or lower, then she is probably not doing the test correctly (unless she is extremely frail and sickly). Check to make sure that she understands to HUFF as hard as she can and make sure she is making a tight seal around the mouthpiece. On the other hand, if the participant is getting very high values, say in the high 400s, she may also be doing the test incorrectly, by blowing out too much air instead of just ONE BIG HUFF. These participants may also just have great pulmonary function but if you're consistently getting values in the high 400s then double check your instructions and demonstrations. Please watch for these common errors.

Be sure to use the exact same script and level of enthusiasm with all participants as this exam is easily influenced by the directions given as well as by how much the participant is encouraged to blow hard. The script should be read exactly as written above. Most important are the lines describing how hard to blow out: " HUFF as hard as you can. Just one big huff and stop blowing before you've completely run out of air." These 2 sentences should be read exactly as written. Please try to give instructions with "moderate" enthusiasm - i.e. encourage the participant to perform well but don't overdo it.

Remove and dispose of the mouthpiece after each participant in front of the participant.

You may tell the participant her flow rate (the highest one), and the average for women her age and size.

4. Potential Problems

If the participant can not stand, have her perform the test sitting, or if necessary, lying down. Record this information.

If the participant coughs or becomes breathless, let her rest between blows.

Make sure she holds it at the bottom; otherwise, the dial may be blocked.

Watch for air leaks. These may be a particular problem in a woman with ill-fitting dentures; it may be necessary to ask her to remove them.

Record your subjective judgment about whether the participant had difficulty with this procedure on the examination form.

5. Instrument calibration.

The flow meter is calibrated at the factory, and is intended for several hundred uses.

Self-calibrate the home visit flow meter biweekly as long as home visits are being conducted.

The devices are inexpensive and sturdy enough so that they can be taken on home visits.

AVERAGE PEAK FLOW RATES (L/MIN) IN WOMEN

Age (years)	Body size *Large*	*Medium*	*Small*
70	330	311	294
75	300	281	264
80	269	251	234
85	239	221	204
90	209	191	174

Large = 5' 6", 184 pounds (90th percentile for both)
Medium = 5' 3", 147 pounds (mean)
Small = 5" 0", 116 pounds (10th percentile for both)

Based on prediction equations in Am J Epidemiol 1989; 130:66-78, and SOF baseline data for height and weight.

Values within 80 ml of the means are within 2 SD.

Note that these are lower than those on the chart that comes with the flow meter.

D. BIOLOGICAL SPECIMENS

I. BLOOD DRAW - HOME VISIT

1. Introduction

Blood draw should be coordinated so that the blood has adequate time to clot at room temperature but also to minimize the length of time on ice before processing at the clinic.

The home visit blood draw protocol is the same as that protocol followed in the clinic except that the processing (centrifuging, pipetting, and freezing) will be delayed.

2. Equipment

Gloves, disposable, non-sterile
4 ml cryotubes for storage and shipping.
10 ml red-top tubes, non-coated (BD #6441), 2 per subject
Vacutainer set-ups; 20 or 21 g needles
Wooden applicator sticks
Color cap inserts (white) for the 4 mL cryotubes
Plastic disposable transfer pipettes (with built in bulbs)

3. Procedures

A. Venipuncture

PUT ON GLOVES

a) Before drawing the blood, a preprinted label showing the participant's ID code should be placed on each vacutainer tube. It is essential to then check the ID code on each tube to ensure that the specimen being collected belongs to the participant. This can best be done by holding the tube next to the ID number on the participant's chart and calling out the number. Then ask the participant to say her name aloud and verify it against the name on the chart.

b) Draw blood from an antecubital vein whenever possible. Use a tourniquet to produce venous distention so that a needle can be inserted. A blood pressure cuff inflated midway between systolic and diastolic blood pressure is most effective and is highly recommended. Do not leave the tourniquet in place for more than 2 minutes. This avoids excessive hemoconcentration. If the 2 minute interval is exceeded, abandon the arm temporarily and attempt to obtain the specimen from the other arm.

c) Draw blood using the vacutainer system (2 10 mL tubes for BRI). For detailed instructions, use those supplied with the vacutainer tubes. A syringe may be used for participants with veins that are too small or fragile for the vacutainer system.

d) Allow the filled red-top tubes to stand at room temperature for 20 - 40 minutes. This procedure is necessary to allow an adequate clot to form. Record on the home visit cover page the time the blood was drawn.

e) Once the clot has formed (after no more than 40 minutes), put the blood on ice. Return to the clinic as soon as possible and once at the clinic, immediately resume processing of the blood following SOF visit 4 protocol for serum processing. Record on the home visit cover page the time that the blood was processed.

B. BLOOD PROCESSING AT THE CLINIC - RED TOP TUBES

PUT ON GLOVES

a) Allow the filled red-top tubes to stand at room temperature for 20 - 40 minutes. This procedure is necessary to allow an adequate clot to form.

b) After clot formation and before centrifugation, remove the red-top stoppers and gently free the clot from the sides of the tube with a clean plain wooden applicator stick. Replace the stoppers. Balance the tubes of blood for centrifugation. Use a horizontal centrifuge; angle heads are not satisfactory.

c) Centrifuge the blood for 10 minutes at room temperature at a setting known to yield a relative centrifugal force (RCF) of at least 1000 x g at the bottom of the tubes. The table below gives those combinations of centrifuge speed in revolutions per minute (rpm) and rotating radius (r) that will yield an RCF value of 1000 x g. RPM should be read from a tachometer or rev counter when the centrifuge is normally loaded. Radius (r) is measured in centimeters from the center of the rotor shaft to the bottom of the vacutainer tube when the tube is in a horizontal position.

r (cm)	12	14	16	18	20	22.5	26
rpm	2800	2600	2400	2250	2100	2000	1900

Do not use a brake to slow down the centrifuge.

d) Remove serum from the clot by aspiration with a clean transfer pipet (the clot may sometimes stick to plastic). Use a new pipet for each subject. Transfer the serum to prelabeled (see e. below) cryotube with white stopper insert. Fill the cryotube up to the line that is already marked on the tube (this yields 3.6 to 4 mL). Do not go above this line because expansion space is needed when the serum freezes. If there is not enough serum to fill the tube, fill it as much as possible. If there is enough serum, make 2 tubes of serum.

e) Each cryotube should be individually labeled with the ppt ID and filled with serum. Use a pen with permanent ink. "Sharpies" work best. Keep the labeled cryotubes away from solvents such as alcohol or acetone as these will erase the ID code. Before transferring the serum, the vacutainer tube and cryotube should be held side by side and the numbers read aloud to check that the ID code numbers match. Do not set up production lines of labeled empty cryotubes. This increases the chance of error.

f) If the serum is reddish in color, determine if it is hemolyzed or simply contaminated with red blood cells. One can tell the difference by recentrifuging the vacutainer tube. This will pellet any contaminating red cells and the serum will clear. If the sample is hemolyzed the red color will remain in the serum. If the patient is still in the clinic, another red-top tube should be obtained. Otherwise, the hemolyzed sample should be processed.

g) Insert the white insert into the serum cryotube cap. Some caution should be used in capping the cryotubes. Screw the caps on firmly to secure them tightly against the rubber gasket, but do not apply an extreme amount of pressure. To promote rapid freezing, place the cryotubes upright in a footless metal rack that is in contact with a shelf in a -20 C freezer.

h) Blood processing should be completed and tubes placed in cold storage first thing after returning to the clinic.

5. Summary of Important Rules

a) The tourniquet must not be in place for more than 2 minutes.

b) The tourniquet must be released before blood is drawn.

c) Vacutainer tubes and cryotubes must be pre-labeled with the participant's ID code number. Vacutainer tube ID numbers must be checked with the participant's chart immediately before venipuncture. Cryotube ID numbers must be checked with each respective vacutainer tube before transferring the samples.

d) The red-top vacutainer tubes must be kept at room temperature for at least 20 minutes but no longer than 40 minutes before putting on ice.

e) Blood processing should be completed and serum stored in the freezer as soon as possible after returning to the clinic.

f) Time the blood was drawn and time the blood was processed should be recorded on the home visit examination cover page.

II. URINE PROTOCOL - HOME VISIT

1. Introduction

Home visit urine samples will follow the same protocol as clinic specimens except that they will be kept on ice until they arrive at the clinic. Once at the clinic, the urine should be pipetted and frozen in preparation for shipment to BRI.

The purpose of urine samples is to identify women who lose bone most rapidly. The amount of calcium in the urine may be a measure of the rate of bone loss. Other markers of bone loss are being developed; we will preserve the samples for several years until the best potential markers have been developed.

2. Equipment

- Plastic urine containers (clean catch containers used in FIT are fine).
- 4 ml tubes for storage and shipping.
- Color cap inserts (green) for the cryotubes containing urine.

3. Preparation of participants

We will be doing "spot" urine - just a regular collection of urine from the participants that does not require a prolonged collection. When scheduling the home visit, inform all participants that we will be collecting a urine specimen. Again, we'd prefer a first or second void. On the day of her visit, the participant should collect a first void specimen and keep it refrigerated until it is collected by the home visit examiner.

4. Collecting the specimen

If a participant did not collect a first void specimen, collect a specimen during the visit. Determine whether it is a first, second, or greater void and mark the form appropriately. Urine collected after the second void, even if collected during the afternoon, will still be stored and analyzed.

Urine will be collected in clean catch containers as used in FIT. Store the urine in a plastic urine container.

Keep the urine specimen refrigerated until the end of the home visit. Put the urine specimen on ice along with the blood until returning to the clinic. Once at the clinic, the urine should be thawed and then prepared for shipment according to original SOF protocol, listed below.

5. Measuring, freezing and shipping the urine specimen

Take a 4 ml sample for storage in the cryotube. Pipette about 3.6 ml of urine into 4 ml cryotubes (same as used for serum) and fill them in the same way as the serum, leaving at least 10% unfilled to prevent breaking the tubes during freezing. Use a green cap insert to mark the urine tube.

Each cryotube should be individually labeled with the ppt ID and filled with urine. Use a pen with permanent ink. "Sharpies" work best. Keep the labeled cryotubes away from solvents such as alcohol or acetone as these will erase the ID code. Before transferring the urine, double check that the ID code number on the urine cryotube is correct.

The urine sample in the cryotube should be frozen at -20° C as soon as possible. The urine tubes should be labeled, stored at -20° C, just as you do with serum, and shipped with regular shipments to BRI. Altogether, home visit participants will have two tubes to be shipped to BRI: one serum and one urine. If enough serum is collected, make 2 tubes of serum.